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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,761	05/14/2001	Moon Hae Sunwoo	X-9338	6883

7590

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/853,761

Applicant(s)

SUNWOO ET AL.

Examiner

Humera N Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### **Status of the Application**

Acknowledgement is made of the receipt of the IDS filed 01/11/02.

Claims 1-37 are pending. Claims 1-37 are rejected.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 4, 15, 27, 32 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "including" in claims 1, 4, 15, 27, 32, 33 and 35 is indefinite because it is unclear as to which additional components, aside from the cortical/cancellous layers and hyaluronic acid and derivatives, are contained or added in the flexible bone sheet composition. It is suggested that the term "including" be either positively recited or deleted.

The term "about" in claims 1, 2, 3, 4, 7, 15, 16, 17, 27, 32, 33, 35 and 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it is unclear as to the specified ranges intended. It is suggested that the term "about" be either positively recited or deleted.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 4 are rejected under the judicially created doctrine of double patenting over claims 1 and 10 of U. S. Patent No. 6, 326,018 B1 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:

The instant claim 1 of 09/853,761 application is the species in relation to the generic claim 1 of US Pat. No. 6, 326, 018 B1. Claim 1 of Pat. No. 6, 326,018 B1 is broader in scope than instant claim 1 of 09/853,761 application, which is narrower in scope since the generic claim does not recite a thickness of the bone sheet and instant claim 1 recites a specified thickness of 2.0mm to about 8.0mm.

Instant claim 1 of 09/853,761 application is generic in relation to the species of claim 10 of US Pat. No. 6, 326,018 B1. Instant claim 1 comprises cortical and cancellous layers, whereas claim 10 recites a corticocancellous bone powder. Furthermore, the species embraced in US Pat. No. 6,326,018 B1 is embodied in generic claim 1 of 09/853,761.

Instant claim 4 of 09/853,761 application is the species in relation to generic claim 1 of US Pat. No. 6, 326,018 B1. Generic claim 1 comprises hyaluronic acid whereas instant claim 4 also comprises hyaluronic acid. The instantly claimed species embraced in claim 4 of 09/853,761 is embodied in generic claim 1 of US Pat. No. 6, 326,018 B1.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application, which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-9, 11-14, 27-31, 34, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce *et al.* (US Pat. No. 5, 899,939).

Boyce et al. teach a flexible bone sheet for use in the repair, replacement and/or augmentation of various portions of animal or human skeletal systems comprising a unitary structure of two or more layers: a demineralized cortical layer and another layer of a different material, wherein the thickness of the layers range from about 0.5 mm to 20 mm (see reference column 1, lines 1-17); (column 3, lines 11-40).

Boyce et al. while teaching a demineralized cortical bone sheet do not explicitly teach the specified residual calcium weight percentages. It would have been obvious to one of ordinary skill in the pharmaceutical art to determine suitable residual calcium percentages through routine or manipulative experimentation.

Boyce et al. while teaching a bone sheet are lacking in that they do not explicitly teach a sterile bone sheet. It is deemed obvious to one of ordinary skill in the art to apply only sterile materials when used for implantation into human or animal skeletal systems.

Claims 4, 10, 15-26, 32, 33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce et al. ('939) in view of Boyce et al. (US Pat. No. 6, 294,187 B1), hereinafter ('187).

Boyce et al. ('939) while teaching a multi-layered flexible bone sheet comprising a demineralized cortical layer and an additional layer do not explicitly teach hyaluronic acid in the bone composition.

Boyce et al. ('187) teach an osteoimplant bone composition for use in the repair, replacement and/or augmentation of various portions of animal or human skeletal

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systems comprising demineralized cortical and cancellous portions, wherein mucopolysaccharides can be added to the bone composition (see reference column 9, lines 6-15). Therefore, it would have been obvious to one of ordinary skill in the art to add a mucopolysaccharide in a bone composition, which is a suitable biostatic/biocidal agent used to prevent contamination, with the expected result of obtaining a bone particle composition that contains a minimal amount of bacteria and aids in bone formation.

Boyce ('187) do not teach the instantly claimed molecular weights of hyaluronic acid. One of ordinary skill in the art would determine suitable molecular weights through routine experimentation.

### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE  
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